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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,185	06/01/2001	David M. Stern	0575/64080/JPW/SHS/ALB	2919

7590 03/04/2004

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,185

Applicant(s)

STERN ET AL.

Examiner

Jegatheesan Seharaseyon

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 7-13 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 7-13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 9/22/03.

Applicant has cancelled claims 4-6 and 19-25. Claims 3, 7, 9, 11-13, 16 and 17 have been amended. Claims 1, 2, 14 and 15 are withdrawn from further consideration. Thus, claims 3, 7-13 and 16-18 are pending and examined.

2. Applicants correction of the title is acknowledged.

3. It is noted that the Applicant has provided corrected drawings in response to the previous Office Action.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

5. Applicants have amended and cancelled the claims, thus necessitating the withdrawal of the objection of claims 7, 9, 11-13 and 16-25.

Claim Rejections - 35 USC § 112, withdrawn.

6. Rejection of claim 5 as vague and indefinite under 35 USC § 112 2nd paragraph is withdrawn in view of Applicant canceling the claim.

Claim Rejections - 35 USC § 112 1st paragraph, withdrawn

7. Rejection of claims 3-5 and 16-25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirement, is withdrawn in view of Applicant's amendment, remarks and canceling of claims. Specifically the enablement rejection is withdrawn in light of Applicant canceling the claims (19-25) that were reciting diseases with no nexus between the diseases and its relationship with RAGE/ligand.

Claim Rejections - 35 USC § 103, maintained

8. Rejection of claims 3-11 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) in view of Ritthaler et al. (1995) is maintained for reasons of record of the Office Action of 6/17/2003. Applicant's arguments, filed 9/22/03, with respect to rejection of claims 3-11 has been considered fully but is not persuasive.

Although Applicant asserts that the invention is based on the surprising discovery that inhibiting the interaction of RAGE and either AGE or EN-RAGE is useful in treating inflammation, there is no fact or evidence provided to support the assertion (see page 12 of the remarks). Applicants' position that prior to Applicants' discovery, there was no reasonable expectation that inhibiting the interaction of RAGE and either AGE or EN-RAGE would succeed in treating inflammation is not persuasive because Ritthaler et al. (1995) clearly implicated RAGE/AGE interaction in inflammation related pathology.

Moreover, with reference to Applicants' position that the obviousness rejection contradicts with enablement rejection (see page 13 of the remarks), the Office sees no contradiction because, the Office in its scope of enablement rejection (page 9 of June, 17 Office Action) indicated that the claims were enabling for a method of treatment of delayed-type hypersensitivity, collagen-induced arthritis, rheumatoid arthritis and periodontal diseases and non-enabling for other recited diseases. In addition, contrary to Applicants' assertion that the Office is requiring experimental data, Office only stated that there was "no disclosure to indicate that inhibiting the interaction between RAGE and its ligand will treat the diseases listed and there was no nexus established to indicate that the interaction between RAGE and its ligand caused these diseases".

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Although data would be one way to overcome the rejection, it is not required. Therefore, rejection of claims 3-11 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) in view of Ritthaler et al. (1995) is maintained.

9. Rejection of claims 12, 13 and 16-18 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) in view of Ritthaler et al. (1995) and Baker et al. (U.S. Patent No: 5, 998, 408) is maintained for reasons of record of the Office Action of 6/17/2003. Applicant's arguments filed 9/22/03, with respect to rejection of claims 12, 13 and 16-18 has been considered fully but is not persuasive.

Although, Applicant asserts that the invention is based on the surprising discovery that inhibiting the interaction of RAGE and either AGE or EN-RAGE is useful in treating inflammation there is no fact or evidence provided to support that assertion (see page 15 of the remarks). Therefore, rejection of claims 12, 13 and 16-18 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) in view of Ritthaler et al. (1995) and Baker et al. (U.S. Patent No: 5, 998, 408) is maintained.

Double Patenting rejection, maintained

10. Provisional rejection of claim 3-11 and 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 47, 50, 55-60, 62-65 and 67 of copending Application No. 09/167705 in view of Morser et al. (U. S. Patent No: 5, 864,018) and of Ritthaler et al. (1995) is maintained for reasons of record of the Office Action of 6/17/2003. Although, Applicant has indicated that that a terminal disclaimer will be filed, none has been filed yet, thus the rejection is maintained.

11. No claims are allowable.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

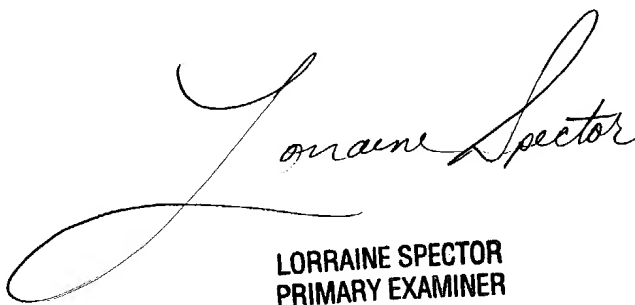
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS



LORRAINE SPECTOR
PRIMARY EXAMINER